yet available. The component of a preservative system whether hexachlorophene or other antimicrobial agent, should be selected on the basis of the effect on the total microbial ecology of the product, not merely on gram-positive bacteria.

(1) Adequate safety data do not presently exist to justify wider use of hexachlorophene in cosmetics.

(2) Antibacterial ingredients used as substitutes for hexachlorophene in cosmetic products, and finished cosmetic products containing such ingredients, shall be adequately tested for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing may be adulterated and will in any event be deemed misbranded unless it contains a conspicuous front panel statement that the product has not been adequately tested for safety and may be hazardous.

(f) *Content statement.* All reference to hexachlorophene limit in this order is on a weight-in-weight (w/w) basis. Quantitative declaration of hexachlorophene content on the labeling of the products, where required, shall be on a w/w basis.

(g) *Shipments of products.* Shipments of products falling within the scope of paragraphs (c), (d), or (e) of this section which are not in compliance with the guidelines stated herein shall be the subject of regulatory proceedings after the effective date of the final order.

(h) *Prior notices.* This order preempts any conditions for marketing products set forth in the following prior notices.

1. DESI No. 4749 (34 FR 15389, October 2, 1969), ''Certain OTC Drugs for Topical Use.''
2. DESI No. 2855 (35 FR 12423, August 4, 1970), ''Certain Mouthwash and Gargle Preparations.''
3. DESI No. 8940 (36 FR 14510, August 6, 1971), ''Topical Cream Containing Pyrilamine Maleate, Benzocaine, Hexachlorophene, and Cetrimonium Bromide.''
4. DESI No. 6615 (36 FR 18022, September 8, 1971), ''Deodorant/Antiperspirant.''
5. DESI No. 6270 (36 FR 23330, December 8, 1971), ''Certain Preparations Containing Hexachlorophene''.

[40 FR 14033, Mar. 27, 1975, as amended at 42 FR 63773, Dec. 20, 1977; 55 FR 11577, Mar. 29, 1990]

EFFECTIVE DATE NOTE: At 67 FR 4906, Feb. 1, 2002, §250.250 was amended in the last sentence of paragraph (c)(1) by removing the phrase ''legend 'Caution: Federal law prohibits dispensing without a prescription,''' and by adding in its place the phrase ''statement 'Rx only,'''' and in paragraph (c)(4)(i) by removing the phrase ''prescription legend'' and by adding in its place the phrase ''statement 'Rx only' '', effective Apr. 2, 2002.

PART 290—CONTROLLED DRUGS

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

AUTHORITY: 21 U.S.C. 352, 353, 355, 371.

SOURCE: 40 FR 14040, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§290.1 Controlled substances.

Any drug that is a controlled substance listed in schedule II, III, IV, or V of the Federal Controlled Substances Act or implementing regulations must be dispensed by prescription only as required by section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act unless specifically exempted in §290.2.

[67 FR 4906, Feb. 1, 2002]

EFFECTIVE DATE NOTE: At 67 FR 4906, Feb. 1, 2002, §290.1 was added; effective Apr. 2, 2002.

§290.2 Exemption from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to a compound, mixture, or preparation containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams that also includes one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer